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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
BELYAVSKYI, MICHAIL A	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 11/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/668,214	SMITH ET AL.	
	Examiner	Art Unit	
	Michail A. Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *09 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46-86* is/are pending in the application.

4a) Of the above claim(s) *64,65 and 84-86* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *46-63 and 66-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 46-86 are pending.

2. Applicant's election with traverse of Group VI claims 46-63,66-83 in the reply filed on 09/09/05 is acknowledged. Applicant traverse the Restriction Requirement on the grounds that the search of Groups I-VI together would not constitute a serious search burden on the examiner and that search of the claims of Group VI would provide useful information for the claims of Group I-V.

This is not found persuasive because the MPEP 803 (August 2001) states that "For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search". The Restriction Requirement enunciated in the previous Office Action meets this criteria and therefore establishes that serious burden is placed on the examiner by the examination of more than one Group. The Inventions are distinct for reasons elaborated in paragraphs 3-5 of the previous Office Action and above

The requirement is still deemed proper and is therefore made FINAL.

Claims 64,65 and 84-86 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 46-63 and 66-83 read on method of generating tissue in a patient, and a method of providing a therapeutic benefit to a patient each comprising culturing mesenchymal cells in a liquid culture medium which is replaced at a rate of at least 25% daily for more than one day and transferring said cultured cells into said patient are under consideration in the instant application.

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed.*

4. It is noted that the Brief Description of the Figures, disclosed Figure 1, panels A-D, Fig.2 panel A-B; Fig.3, panel A-B and Fig.4, panel A-B. There is no said panels in the submitted figures.

5. Applicant is advised that should claims 48 and 68 be found allowable, claims 56 and 76 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

6. The following is a quotation of the second paragraph of 35 U.S.C. 112.
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 72 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Dependent claim 72 recites "wherein the tissue formed is any...". There is insufficient antecedent basis for this limitation in the claims, since base Claim 66 does not recite tissue.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 46-63 and 66-83 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a New Matter rejection**.

" A method of generating tissue in a patient, comprising culturing mesenchymal cells in a liquid culture medium which is replaced at a rate of at least 25% daily for more than one day and transferring said cultured cells into said patient, wherein the tissue formed is any of human tissue selected from the group as recited in claim 52, claimed in claims 46- 63 or " A method of providing a therapeutic benefit to in a patient, comprising culturing mesenchymal cells in a liquid culture medium which is replaced at a rate of at least 25% daily for more than one day and transferring said cultured cells into said patient, wherein the tissue formed is any of human tissue selected from the group as recited in claim 72, claimed in claims 66-83 represent(s) a departure from the specification and the claims as originally filed and applicant has not pointed out where the support come(s) from.

The specification and the claims as originally field only support " A method for obtaining lineage committed human cell with enhanced biological function and/or enhanced proliferation each comprising culturing mesenchymal cells in a liquid culture medium which is replaced at a rate from 25% to 100 % daily for more than one day.

11. Claims 46-63 and 66-83 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for obtaining lineage committed human cell with enhanced biological function and/or enhanced proliferation, wherein human cells are lineage committed hematopoietic cells and dendritic cells (DC) and wherein said biological function is ability of DC to stimulate T-cells *in vitro* , does not reasonably provide enablement to : (i) a method of generating tissue in a patient, comprising culturing mesenchymal cells in a liquid culture medium which is replaced at a rate of at least 25% daily for more than one day and transferring said cultured cells into said patient, wherein the tissue formed is any of human tissue selected from the group as recited in claim 52, claimed in claims 46- 63 or (ii) a method of providing a therapeutic benefit to in a patient, comprising culturing mesenchymal cells in a liquid culture medium which is replaced at a rate of at least 25% daily for more than one day and transferring said cultured cells into said patient, wherein the tissue formed is any of human tissue selected from the group as recited in claim 72, claimed in claims 66-83.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims as written encompass the genus of a methods of generating any human tissue.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the limited working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

The specification only discloses detailed *in vitro* studies of: (i) enhanced proliferative potential of T cells that may produce higher levels of particular cytokines on per cell basis (see Examples 1 and 2 in particular) and (ii) the enhanced ability of DC that were cultured under very specific growth condition in the alloMLR compared to dendritic cells grown under static culture conditions to stimulate T-cells (see example 3 in particular).
The specification does not adequately teach how to effectively: (i) generate tissue in a patient, comprising culturing mesenchymal cells in a liquid culture medium which is replaced at a rate of at least 25% daily for more than one day and transferring said cultured cells into said patient, wherein the tissue formed is any of human tissue selected from the group as recited in claim 52, claimed in claims 46- 63 or (ii) provide a therapeutic benefit to in a patient, comprising culturing mesenchymal cells in a liquid culture medium which is replaced at a rate of at least 25% daily for more than one day and transferring said cultured cells into said patient, wherein the tissue formed is any of human tissue selected from the group as recited in claim 72, claimed in claims 66-83. Applicant has not exemplified any *in vivo or in vitro* studies, wherein any tissue have been generated using claimed method or any therapeutic benefits to a patient have been shown. Moreover, no animals models were used to effectively use: (i) a method of generating tissue in a patient, comprising culturing mesenchymal cells in a liquid culture medium which is replaced at a rate of at least 25% daily for more than one day and transferring said cultured cells into said patient, wherein the tissue formed is any of human tissue selected from the group as recited in claim 52, claimed in claims 46- 63 or (ii) a method of providing a therapeutic benefit to in a patient, comprising culturing mesenchymal cells in a liquid culture medium which is replaced at a rate of at least 25% daily for more than one day and transferring said cultured cells into said patient, wherein the tissue formed is any of human tissue selected from the group as recited in claim 72, claimed in claims 66-83. Peshwa (WO'97/03186) teaches that there appear to be a significant difference in the characteristics of dendritic cells their function and properties (see entire document, page 2 in particular). Engleman (WO 97/22349) teaches that biological function of dendritic cells depends on the tissue from which they were separated and that depending on cultured conditions the function may be different and that *in vitro* data does not always correlates with in vivo studies of human dendritic cells (entire document, page 6 in particular) . In addition, Cochlovius et al (Modern Drug Discovery, 2003, pages 33-38) teach that in contrast to in vitro models, and partly animal-human xenograft systems, tissue cells in vivo seems to express molecules for defense against cellular immune systems as well as against complement. Although these defense mechanisms are still poorly understood, they provide some hints as to why many potential therapeutics perform marvelously *in vitro* but a fairly high portion of them still fail *in vivo*.

Since there is no *in vivo* studies and data in the specification to show the effectively of (i) a method of generating tissue in a patient, comprising culturing mesenchymal cells in a liquid culture medium which is replaced at a rate of at least 25% daily for more than one day and transferring said cultured cells into said patient, wherein the tissue formed is any of human tissue selected from the group as recited in claim 52, claimed in claims 46- 63 or (ii) a method of providing a therapeutic benefit to in a patient, comprising culturing mesenchymal cells in a liquid culture medium which is replaced at a rate of at least 25% daily for more than one day and transferring said cultured cells into said patient, wherein the tissue formed is any of human tissue

selected from the group as recited in claim 72, claimed in claims 66-83, it is unpredictable how to correlate *in vitro* results with *in vivo* use. This, although the Specification describes certain *in vitro* experiments, there is no correlation on this record between *in vitro* experiments and in vivo use. It is not enough to rely on in vitro studies where, as here, a person having ordinary skill in the art has no basis for perceiving those studies as constituting recognized screening procedures with clear relevance to efficacy in humans or animals (emphasis added). Ex parte Maas, 9 USPQ2d 1746.

Thus, Applicant has not provided sufficient guidance to enable one skill in the art to use claimed (i) a method of generating tissue in a patient, comprising culturing mesenchymal cells in a liquid culture medium which is replaced at a rate of at least 25% daily for more than one day and transferring said cultured cells into said patient, wherein the tissue formed is any of human tissue selected from the group as recited in claim 52, claimed in claims 46- 63 or (ii) a method of providing a therapeutic benefit to in a patient, comprising culturing mesenchymal cells in a liquid culture medium which is replaced at a rate of at least 25% daily for more than one day and transferring said cultured cells into said patient, wherein the tissue formed is any of human tissue selected from the group as recited in claim 72, claimed in claims 66-83 in manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement. *In re Fisher*, 166 USPQ 18(CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

In view of the quantity of experimentation necessary, the unpredictability of the art, the lack of sufficient guidance in the specification, the limited working examples, and the limited amount of direction provided given the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 46-63 and 66-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,994,126 or US Patent 5,437,994 each in view of a teaching of the instant Specification on page 11, first paragraph and Smith et al. (Blood, 1997, V.90, NO.10 page 347B) and

US Patent '126 teaches a method of obtaining lineage committed human cells comprising culturing said cells under physiologically acceptable liquid culture conditions including replacement of the liquid culture medium at a rate and for a time sufficient to obtained cells suitable for various immunological intervention and treatment of diseases and transferring said cultured cells into a patient (see entire document, column 12, lines 55-65, column 13, lines 10-25, column 15, line 54-65 and column 21, line 29-35 in particular). US Patent '126 teachers that media replaced every other day for about $5x10^5$ cells/ml culture(see column 17, lines 60-65 and Example 1 in particular). US Patent '126 teachers that culture medium is any culture medium suitable for growing human cells for example RPMI (see column 16, lines 15-65 and Examples 1 and 2 in particular) . Said medium would obviously contained animal serum , glucose, lactate, glutamine and ammonia. It is noted that US Patent '126 teaches does not explicitly teaches that said cells have an enhanced biological function as compared to the function of the lineage committed cell cultured *ex-vivo* under conditions which do not include replacement of the liquid culture. However, it is noted that the referenced cells are human cells that have been cultured under the same culturing conditions as claimed thus obviously would have an enhanced biological function *in vitro*. Moreover, it is noted that the specification on page 11, first paragraph disclosed that one skill in the art will readily appreciate that the term "biological function" refers to ability of a cell population to carry out its biological missions, i.e. for example the ability to proliferate leading to development/regeneration of tissue. Thus, it would be immediately obvious to one skill in the art that the referenced cell with enhanced biological function includes the ability to generate tissue. It is also noted Discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. " The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art". See MPEP 2112.02. Also, see Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. 58 USPQ2d 1508 (CA FC 2001); Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed.

US Patent '994 teaches a method of obtaining lineage committed human cells comprising culturing said cells under physiologically acceptable liquid culture conditions including replacement of the liquid culture medium at a rate and for a time sufficient to obtained cells suitable for various immunological intervention and treatment of diseases and transferring said cultured cells into a patient (see entire document, column 4, lines 40-65overlapping columns 5 and 6 in particular). US Patent '994 teachers that media is replaced either continuoulsly or periodically for the cell culture at a density of $2x10^4$ to $2x10^6$.(see column column 6, lines 1-10

and overlapping columns 16-18 in particular). US Patent '994 teachers that culture medium is any culture medium suitable for growing human cells for example DMEM, IMDM, RPMI (see column 5, lines 25-40, overlapping columns 8-15 in particular) . Said medium would obviously contained animal serum , glucose·lactate glutamine and ammonia. It is noted that US Patent '994 does not explicitly teaches that said cells have an enhanced biological function as compared to the function of the lineage committed cell cultured *ex-vivo* under conditions which do not include replacement of the liquid culture. However, it is noted that the referenced cells are human cells that have been cultured under the same culturing conditions as claimed thus obviously would have an enhanced biological function *in vitro*. Moreover, it is noted that the specification on page 11, first paragraph disclosed that one skill in the art will readily appreciate that the term "biological function" refers to ability of a cell population to carry out its biological missions, i.e. for example the ability to proliferate leading to development/regeneration of tissue. Thus, it would be immediately obvious to one skill in the art that the referenced cell with enhanced biological function includes the ability to generate tissue. It is also noted Discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. " The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art". See MPEP 2112.02. Also, see Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. 58 USPQ2d 1508 (CA FC 2001); Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed.

The claimed invention differs from the reference teaching in that US Patent '126 and US Patent '994 does not explicitly teach that the culture medium is replaced daily at the rate of at least 25%, 50% to 100% for the cell density from $1x10^4$ to $1x\ 10^7$ cell per ml of culture .

Smith et al., teach an advantage of using culture medium condition wherein medium is replaced at certain rate compare to static conditions to generate human cells with enhanced biological function (see entire document). Moreover, Smith et al., further teach that said continuously perused system was set to evaluate the effects of frequent medium exchange on dendritic cell expansion and biological function.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of Smith et al., to those of US Patent '126 and US Patent '994 to obtain a claimed method of generating tissue in a patient wherein culture medium is replaced daily at the rate of at least 25%, 50% to 100% for the cell density from $1x10^4$ to $1x\ 10^7$ cell per ml of culture. It would be conventional and within the skill of the art to determine the optimum rate of replacement of the medium that will result in enhanced biological function of cultured committed dendritic cells. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because using culture medium condition wherein medium is replaced at certain rate compare to static conditions to generate human cells with enhanced biological function as taught by Smith et al., and can be used in the method taught by US Patent '126 and US Patent '994. The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. In re Semaker. 217 USPQ 1, 5 - 6 (Fed. Cir. 1983). See MPEP 2144.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Thus, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 46-63 and 66-83 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-7, 10-12, 38-41, 49-58 and 60-65 of copending Application No. 09/027,671 as is evidenced by disclosure of the specification on page 11 first paragraph. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 6-7, 10-12, 38-41, 49-58 and 60-65 of copending Application No. 09/027,671 recites a method of obtaining lineage committed human cells with enhanced biological function comprising culturing said cells under physiological conditions , said conditions including daily replacement a liquid culture medium at a rate from 50 to 100% for a cell density from $1x10^4$ to $1x10^7$ cell per ml of culture.

As is evidenced by the disclosure of the specification on page 11 first paragraph, the term "biological function" refers to ability of a cell population to carry out its biological missions, i.e. for example the ability to proliferate leading to development/regeneration of tissue. Thus, it would be immediately obvious to one skill in the art that the referenced cell with enhanced biological function includes the ability to generate tissue.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claim 46-63 and 66-83 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,835,566 as is evidenced by disclosure of the specification on page 11 first paragraph. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims -18 of U.S. Patent No. 6,835,566 recites a method of obtaining lineage committed human cells with enhanced biological function comprising culturing said cells under physiological conditions , said conditions including daily replacement a liquid culture medium at a rate from 25 to 100% for a cell density from $1x10^4$ to $1x10^7$ cell per ml of culture.

As is evidenced by the disclosure of the specification on page 11 first paragraph, the term "biological function" refers to ability of a cell population to carry out its biological missions, i.e. for example the ability to proliferate leading to development/regeneration of tissue. Thus, it would be immediately obvious to one skill in the art that the referenced cell with enhanced biological function includes the ability to generate tissue.

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 571/273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michail Belyavskyi, Ph.D.
Patent Examiner
Technology Center 1600
October 28, 2005